

525 Rec'd PCT/PTO 16 OCT 2000

Practitioner's Docket No. 2260/103**IN THE UNITED STATES DESIGNATED OFFICE (DO/US)**

<u>PCT/IB99/00808</u>	<u>17 February 1999</u>	<u>18 February 1998</u>
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
<u>Process for the Obtaining of HMG-CoA Reductase Inhibitors of High Purity</u>		
TITLE OF INVENTION		
<u>Pflaum et al.</u>		
APPLICANT(S) FOR DO/US		

Box PCT

Assistant Commissioner for Patents  
Washington, D.C. 20231

ATTENTION: DO/US

**COMPLETION OF FILING REQUIREMENTS  
FOR INTERNATIONAL APPLICATION ENTERING NATIONAL  
STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. § 371**

(check and complete the following item, if applicable)

- ☒ This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.494 (FORM PCT/DO/EO/905).
- ☒ A copy of FORM PCT/DO/EO/905 accompanies this response.

**CERTIFICATION UNDER 37 C.F.R. § 1.10\***

(Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date 16 October 2000, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL543500585US, addressed to the: ~~Assistant~~ Commissioner for Patents, Washington, D.C. 20231.

10/18/2000 HBIZUNES 00000019 09600566

01 FC:154  
02 FC:115130.00 CP  
110.00 CP

Timothy M. Murphy

(type or print name of person mailing paper)

Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office  
(DO/US) under 35 U.S.C. § 371 [13-8]—page 1 of 6)

**WARNING:** Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 20 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 1.8(2)(x)).

**NOTE:** Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

## DECLARATION OR OATH

- I. ☒ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

**NOTE:** For surcharge fee for filing declaration after filing date, complete item IV(2).

**NOTE:** Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);

(B) serial number and filing date;

(C) attorney docket number which was on the specification as filed;

(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 601.01(a), 7th ed. Notice of September 12, 1983 (1035 O.G. 3). See M.P.E.P. § 601.01(a), 7th ed.

**NOTE:** Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

**NOTE:** 37 C.F.R. § 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete (a) or (b), if applicable)

Attached is a

- (a) ☐ Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (b) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

## AMENDMENT

II.

(complete as applicable)

- ☐ An amendment in accordance with 37 C.F.R. § 1.121 is attached.
- ☐ The attached amendment cancels claims \_\_\_\_\_ inclusively.

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 2 of 6)

**TRANSMITTAL OF ENGLISH TRANSLATION  
OF NON-ENGLISH LANGUAGE PAPERS**

III. ☐ Submitted herewith, is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. § 1.494(b)(2)).

NOTE: For fee for processing a non-English application, and submission of an English translation later than 20 months after the priority date, complete item IV(3) below.

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).

**FEES****IV.**

NOTE: See 37 C.F.R. § 1.28(a).

**1. Fees for claims**

- ☐ Each independent claim in excess of 3  
(37 C.F.R. § 1.492(b)—\$78.00; small entity—\$39.00) \$ \_\_\_\_\_
- ☐ Each claim in excess of 20  
(37 C.F.R. § 1.492(c)—\$18.00; small entity—\$9.00) \$ \_\_\_\_\_
- ☐ Multiple dependent claim(s)  
(37 C.F.R. § 1.492(d)—\$260.00;  
small entity—\$130.00) \$ \_\_\_\_\_

**2. Surcharge fees**

- ☒ Surcharge set forth in § 1.492(e), for accepting the declaration later than 20 months after the priority date in filing an application in the U.S. as a designated office—\$130.00; small entity—\$65.00 \$ 130.00

NOTE: The processing fee in the next item (Number 3) below is not subject to a reduction for small entity status.

**3.**

- ☐ Processing fee set forth in § 1.492(f), for acceptance of an English translation later than 20 months after the priority date—\$130.00 \$ \_\_\_\_\_
- Total fees \$ \_\_\_\_\_

### SMALL ENTITY STATUS

- V. ☐ A statement that this filing is by a small entity

NOTE: See 37 C.F.R. § 1.28(a).

*(check and complete applicable items)*

- a. ☐ is attached.  
☐ was filed on \_\_\_\_\_ (original).  
b. ☐ A separate refund request accompanies this paper.

### EXTENSION OF TIME

*(complete (a) or (b), as applicable)*

#### VI.

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.136(a) apply.

- (a) ☒ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below

<input checked="" type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 380.00	\$ 190.00
<input type="checkbox"/> three months	\$ 870.00	\$ 435.00
<input type="checkbox"/> four months	\$ 1,360.00	\$ 680.00

Fee: \$ 110.00

If an additional extension of time is required, please consider this a petition therefore.

*(check and complete the next item, if applicable)*

- ☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.  
Extension fee due with this request \$ \_\_\_\_\_

or

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

### TOTAL FEE DUE

#### VII. The total fee due is:

Completion fee(s) \$ 130.00

Extension fee (if any) \$ 110.00

TOTAL FEE DUE \$ 240.00

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 4 of 6)

**PAYMENT OF FEES****VIII.**

- ☒ Enclosed is a check in the amount of \$ 240.00
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_

A duplicate of this request is attached.

**NOTE:** Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

**AUTHORIZATION TO CHARGE ADDITIONAL FEES****IX.**

**WARNING:** Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper, and during the entire pendency of this application, to Account No. 19-4972

☒ 37 C.F.R. §§ 1.492(a)(2), 1.492(a)(3), or 1.492(a)(5) (filing fees)

☒ 37 C.F.R. § 1.492(b) (presentation of extra claims)

**NOTE:** Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

**WARNING:** While 37 C.F.R. § 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. § 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b)).

**NOTE:** Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

**NOTE:** 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 U.S.C. § 371 [13-8]—page 5 of 6)

- ☒ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 20 months from the earliest claimed priority date)

**WARNING:** *It is suggested that you always check this last authorization.*

Reg. No. 33,198

Tel. No.: (617) 443-9292

Customer No.: 002101



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SIGNATURE OF PRACTITIONER

Timothy M. Murphy

(type or print name of practitioner)

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125 Summer Street

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Boston, MA 02110

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office  
(DO/US) under 35 U.S.C. § 371 [13-8]—page 6 of 6)

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BROMBERG & SUNSTEIN

09/600566

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS  
Box PCT  
Washington, D.C. 20231 2260/103

U.S. APPLICATION NO. 002101 50/1 FIRST NAMED APPLICANT PCT/1899/00808  
ATTY. DOCKET NO.

BRUCE D. SUNSTEIN  
BROMBERG & SUNSTEIN, LLP  
125 SUMMER STREET, 11TH FLOOR  
BOSTON MA 02110-1618

INTERNATIONAL APPLICATION NO.  
02/17/99 02/18/98

I.A. FILING DATE U.S. PRIORITY DATE

DATE MAILED 17 AUG 2000

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as

- ☐ a Designated Office (37 CFR 1.494),
- ☒ an Elected Office (37 CFR 1.495):
- ☒ U.S. Basic National Fee.
- ☒ Copy of the international application in:
  - ☐ a non-English language.
  - ☒ English.
- ☐ Translation of the international application into English.
- ☐ Oath or Declaration of inventors(s) for DO/EO/US.
- ☐ Copy of Article 19 amendments.
- ☐ Translation of Article 19 amendments into English.
- ☐ The International Preliminary Examination Report in English and its Annexes, if any.
- ☐ Translation of Annexes to the International Preliminary Examination Report into English.
- ☒ Preliminary amendment(s) filed Jul 19, 2002 and
- ☐ Information Disclosure Statement(s) filed and
- ☐ Assignment document.
- ☐ Power of Attorney and/or Change of Address.
- ☐ Substitute specification filed
- ☐ Verified Statement Claiming Small Entity Status.
- ☒ Priority Document.
- ☒ Copy of the International Search Report and copies of the references cited therein.
- ☐ Other:

2. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. Note a processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
  - ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
- ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
- ☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the international application number and international filing date.
  - ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
- ☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

3. Additional claim fees of \$ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due. See attached PTO-875.

**ALL OF THE ITEMS SET FORTH IN 2(a)-2(d) AND 3 ABOVE MUST BE SUBMITTED WITHIN ONE MONTH FROM THE DATE OF THIS NOTICE OR BY ☐ 21 OR ☒ 31 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

4. Translation of the Annexes **MUST** be submitted no later than the time period set above or the annexes will be cancelled. Note processing fee will be required if submitted later than 30 months from the priority date.

5. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

***A copy of this notice MUST be returned with this response.***

Enclosed:  
☐ PCT/DO/EO/917  
☐ Notice of Defective Translation  
☐ PTO-875  
 FORM PCT/DO/EO/905 (December 1997)

*John Anderson*  
 Telephone: 703 308-9116